



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

November 12, 1999

Thomas Scarlett  
Hyman, Phelps & McNamara, P.C.  
700 Thirteenth Street, N.W.  
Suite 1200  
Washington, DC 20005-5929

Dear Mr. Scarlett:

Your petition requesting the Food and Drug Administration to clarify its informal policy requiring suitability petitions for parenteral drugs where the only change from the listed drug is in the size of the container and not in the strength of the drug was received by this office on November 12, 1999. It was assigned docket number 99P-4932-CP 1 and it was filed on November 12, 1999. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Hyle D. Jaffe  
Dockets Management Branch

99P-4932

ACK 1